

INFORMATION DISCLOSURE
IN AN APPLICATION

(Use several sheets if necessary)

Sheet 1 OF 2

Docket Number
107223.167 US2Application Number
10/630,239Applicant
Sanghvi, et al.Filing Date
July 30, 2003Group Art Unit
~~Not yet assigned~~
1615

U.S. Patent Documents

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
Q/S	5,128,143	7/7/92	Baichwal, et al.	424	464	
	5,135,757	8/4/92	Baichwal, et al.	424	465	
	5,455,046	8/29/95	Baichwal, et al.	424	451	9/8 7/7/06
	5,512,297	4/30/96	Baichwal	424	451	
	5,554,387	9/10/96	Baichwal	424	488	
	5,399,358	3/21/95	Baichwal, et al.	424	464	
	5,399,359	3/21/95	Baichwal	424	464	
	5,670,168	9/23/97	Baichwal, et al.	424	464	
	4,828,836	5/9/89	Elger, et al.	424	419	
	6,340,475	1/22/02	Shell, et al.	424	469	
	4,351,825	9/28/82	Sothmann, et al.	424	19	
	5,055,306	10/8/91	Barry, et al.	424	482	
	5,330,767	7/19/94	Yamamoto, et al.	424	497	
	5,611,971	3/18/97	Maedera, et al.	264	4.1	
	5,631,021	5/20/97	Okada, et al.	424	451	
	5,651,990	7/29/97	Takada, et al.	424	497	
Q/S	3,629,393	12/21/97	Nakamoto, et al.	424	22	

Foreign Patent Documents

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
Q/S	99/47128	9/23/99	WO				
	97/17975	5/22/97	WO				
	44 32 757	3/21/96	DE			YES	
	0 749 751	12/27/96	EP				
	0 580 428	10/1/97	EP				
	0 709 085	5/1/96	EP				
	0 531 497	8/13/97	EP				
Q/S	0 251 459	7/8/92	EP				

Other Documents (Including Author, Title, Date Pertinent Pages, Etc.)

EXAMINER

Sumera N. Reza

DATE CONSIDERED

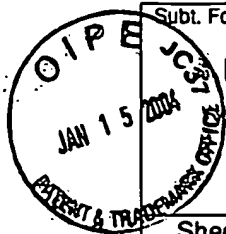
07-07-06

EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP § 609: Draw Line through citation if not conformance and not considered. Include copy with next communication to applicant.

Subt. Form PTO-1449				Docket Number 107223.167 US2	Application Number 10/630,239
INFORMATION DISCLOSURE IN AN APPLICATION Use several sheets if necessary)				Applicant Sanghvi, et al.	
				Filing Date July 30, 2003	Group Art Unit Not yet assigned 1615
Sheet	2	OF	2		

9/8	A1	Campbell, et al., "A Clinical Evaluation of a Delayed Release Preparation of Metformin," <i>J Int Med Res</i> , Vol. 1, pp.551-556 (1973)
	A2	Pentikainen, "Bioavailability of Metformin. Comparison of solution, rapidly dissolving tablet, and three sustained release products," <i>Int J Clin Pharmacol, Ther and Toxicol</i> , Vol. 4, pp. 213-220 (1986)
	A3	Abdallah, et al., "Preparation and evaluation of metformin hydrochloride controlled-release tablets," <i>S.T.P. Pharma</i> , Vol. 4(1), pp. 15-20 (1988)
	A4	Karttunen, et al., "The Pharmacokinetics of metformin: a comparison of the properties of a rapid-release and sustained-release preparation," <i>Int J Clin Pharmacol, Ther and Toxicol</i> , Vol. 21(1), pp. 31-36 (1983)
	A5	Mosby's GenRx, "Drug Names – Metformin Hydrochloride (3204) Categories, Brand Names, Formularies & Cost of Therapy," (1998) pp.1-17
	A6	Saleh, "Tablets produced under licence Do they have the same dissolution characteristics and drug content uniformity as the original ones? Example: metformin hydrochloride sustained-release tablets," <i>S.T.P. Pharma</i> , Vol. 6(8), pp. 598-603 (1990)
	A7	Grdinic, et al., "Comparison of in-vitro release and renal elimination of 1-butylbiguanide from times-release oral antidiabetic preparations," <i>Acta Pharm. Jugoslav.</i> , Vol. 29, pp. 215-221 (1979)
	A8	Dimitrijevic, et al., "Electro-Responsive Release From A Chondroitin Sulphate Hydrogel," <i>J. Pharm. Pharmacol.</i> , Vol. 47, pp. 1058 (1995)
	A9	Karttunen, "The Influence of Pharmaceutical Formulation on the Gastrointestinal Side Effects of Metformin," <i>Scandinavian Society for the Study of Diabetes</i> , 15 th Annual Meeting, Norway (1980)
	A10	Noel, "Kinetic Study of Normal and Sustained Release Dosage Forms of Metformin in Normal Subjects," <i>Research and Clinical Forums</i> , Vol. 1(4), pp. 35-50 (1979)
	A11	Noel, "Kinetic Study of Normal and Sustained Release Dosage Forms of Metformin in Normal Subjects," <i>Journal of International Biomedical Information and Data</i> , Vol. 1(1), pp. 9-20 (1980)
	A12	Bristol-Myers Squibb, "Glucophage XR (Metformin HCl extended-release) Tablets, Rx," <i>FDA Website</i> , (Posted October 20, 2000)
	A13	"Glucophage Retard," <i>The Rote Liste</i> (1993)
	A14	Araman, et al., "In Vivo-In Vitro Correlation of Prolinged Release Metformin HCL Tablets Prepared with Coating Materials," <i>Supplement F, Supplement to Pharmaceutisch Weekblad Scientific Edition, 1st European Congress of Pharmaceutical Science</i> , Vol. 14(5) (1992)
9/8	A15	Stanforth, "Synergistically Interacting Heterodisperse Polysaccharides – Function in Achieving Controllable Drug Delivery," <i>American Chemical Society</i> (1993)

EXAMINER <i>Sumera N. Mehta</i>	DATE CONSIDERED 07-07-06
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Subt. For, PTO-1449		Docket Number 107223.167 (US2)	Application Number 10/630,239
INFORMATION DISCLOSURE IN AN APPLICATION (Use several sheets if necessary)		Applicant SANGHVI, et al.	
		Filing Date July 30, 2003	Group Art Unit 1614 1615
Sheet	1	OF	1

U.S. Patent Documents						
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
MS	5,955,106	9/21/99	Moeckel, et al.	424	464	

Foreign Patent Documents							
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

Other Documents (Including Author, Title, Date Pertinent Pages, Etc.)		

EXAMINER <i>Sumera N. Sheikh</i>	DATE CONSIDERED 07-07-06
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PTO/SB/08a/b (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/630,239-Conf. #9388
				Filing Date	July 30, 2003
				First Named Inventor	Pradeep P. SANGHVI
				Art Unit	1615
				Examiner Name	H. N. Sheikh
Sheet	1	of	1	Attorney Docket Number	0107223.00167US2

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ⁴ -Number ⁵ -Kind Code ⁶ (if known)				

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
g/s	CA	DHOPESHWARKAR et al., Evaluation of Xanthan Gum in the Preparation of Sustained Release Matrix Tablets, Drug Development and Industrial Pharmacy, 19(9), 999-1017 (1993)	

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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	<i>Humera N. Sheikh</i>	Date Considered	07-07-06
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